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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,098	06/14/2001	Beate Diefenbach	MERCK 2251	5446

23599 7590 11/08/2005

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EXAMINER	
HAMIDINIA, SHAWN A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,098	DIEFENBACH ET AL.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants election with traverse of Group I and sequence RTDLYYLRTY in the reply filed on August 29, 2005 is acknowledged. Claims 13-16, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Priority

2. The current application filed on June 14, 2001 claims benefit of a foreign application, 198 58 587.7, filed on December, 19, 1999.

Information Disclosure Statement

3. The information disclosure statement filed June 14, 2001 has been considered. Please see attached initialed PTO-1449s.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The applicant's invention is for a peptide sequence, RTDLYYLRTY, which is suggested to inhibit the $\alpha_v\beta_6$ integrin receptor. The specification contains some discussion of what the inhibition of the $\alpha_v\beta_6$ integrin receptor is expected to do but there is not enough to establish a specific and substantial utility.

As discussed in the specification, the $\alpha_v\beta_6$ integrin receptor binds to the Arg-Gly-Asp (RGD) peptide sequence in the natural ligand fibronectin, see lines 26-28, page 2. The fourth paragraph, page 11 suggests several uses for the elected peptide sequence when it blocks the $\alpha_v\beta_6$ integrin receptor such as a medicament treating: thromboses, cardiac infarct, coronary heart disorders, arteriosclerosis, tumors, osteoporosis, inflammations, infections and for influencing wound healing processes.

Lines 36-1, pages 2-3 of the specification states, "The physiological and pathological functions of $\alpha_v\beta_6$ are still not precisely known; however it is suspected that this integrin plays an important part in physiological processes and disorders binding of fibronectin." The specification does not disclose what the activity of the $\alpha_v\beta_6$ integrin receptor precisely is, beyond the suspicion that this integrin receptor plays an important part in physiological processes and disorders binding to fibronectin. This does nothing to explain what exactly happens when the elected peptide sequence inhibits the $\alpha_v\beta_6$ integrin receptor. Further, Huang et al. teaches that because there is a lack of tools to

specifically inhibit the function of $\alpha_v\beta_6$, little is known about its effects on cell behavior, see summary, page 2189. Additionally, there is no evidence that inhibiting this integrin with the elected peptide would have any effect as a medicament for the control of thromboses, cardiac infarct, coronary heart disorders, arteriosclerosis, tumors, osteoporosis, fibrosis, inflammations, infections, psoriasis and wound healing.

Therefore, the use of the elected peptide lacks a specific and substantial utility in the absence of a disclosure of what the inhibition of the $\alpha_v\beta_6$ integrin receptor actually does.

Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Enablement

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which were not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, for how to use the invention. The specification, while enabling for the peptide sequence of RTDLYYLRTY, does not reasonably provide enablement for how to use the peptide.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because the physiological and pathological role of the $\alpha_v\beta_6$ integrin receptor is uncertain, and it would take many tests and experimental conditions to elucidate its cellular effects when in the normal and inhibited state; (2) there is no guidance provided by the specification since there is no disclosure of what happens when the $\alpha_v\beta_6$ integrin receptor is inhibited. Additionally, (3) the specification does not present any working examples of a

therapeutic affect on the proposed disorders; (4) the nature of the invention is a medicament comprising a polypeptide having the sequence RTDLYYLRTY used to treat thromboses, cardiac infarct, coronary heart disorders, arteriosclerosis, tumors, osteoporosis, inflammations, infections and to influence wound healing processes. The prior art (5) shows; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low with regard to inhibiting the $\alpha_v\beta_6$ integrin receptor because it is physiologically and pathologically unclear what happens when this integrin is blocked. Furthermore, it is unknown if inhibiting the $\alpha_v\beta_6$ integrin receptor will treat the list of proposed disorders. Finally, (8) the claims are extremely broad because the multitude of disorders that the administered peptide sequence is attempting to treat is unsubstantiated and are completely uncharacterized.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is unavoidable.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER